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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/920,342

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Shi-Lung Lin

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06/12/2006

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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,342

Applicant(s)

LIN ET AL.

Examiner

J. D. Schultz, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,34-38,40-45,55,58-61 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,34-38,40-45,55,58-61 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 29 March 2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 27 December 2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claim 37 drawn to an invention nonelected with traverse in Paper No. 6 November 2003. Applicants have traversed the following statement provided in the previous action: "A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01." It is clarified that this is not a request only to cancel claim 37, but to either cancel said claim, or take other appropriate action.

Response to Arguments, Claim Rejections - 35 USC § 102 and 103

Claims 32, 34, 35, 41-43, 55, 58, 59, and 64-66 are rejected under 35 U.S.C. 102(a) as being anticipated by Alexeev et al. (Nature Biotech. 2000, 18:43-47), and is repeated for the same reasons of record as cited in the action mailed 27 December 2005.

Art Unit: 1635

Claims 32, 34-38, 40-45, 55, 58-61 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexeev et al. (cited above) as applied to claims 32, 34, 35, 41-43, 55, 58, 59, and 64-66 above, and further in view of Fire et al. (U. S. Patent Number 6,506,559), and Bennett et al. (U. S. Patent Number 6,066,500), and is repeated for the same reasons of record as cited in the action mailed 27 December 2005.

Applicants primary argument for both rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are based upon the same assertion, namely, that the molecule of Alexeev et al. does not teach an mRNA-cDNA molecule wherein the mRNA is in the sense orientation. Accordingly, responses to both of these arguments have been combined and are presented below.

As set forth in the non-final action of 27 December 2005, Alexeev et al. teach the use of an RNA-DNA oligonucleotide that corrects a point mutation in a mouse gene. Thus, Alexeev et al. is considered to teach a method for inhibiting target gene expression comprising the use of an RNA-DNA hybrid, because expression of the mutated gene was inhibited. The method of Alexeev furthermore targets the gene in vivo. Although Alexeev does not teach that the RNA portion of the oligonucleotide is a full-length mRNA, a full-length mRNA is not considered to be required by the instant claim, because said claim does not recite that the mRNA must be full-length and also because the only examples taught in the instant specification that support the claimed method in vivo utilize a fragment of the coding sequence which itself is not a full-length mRNA. Thus, since the oligonucleotide of Alexeev et al. also uses a fragment derived from the coding sequence of the target gene, the method of Alexeev et al. is considered to be commensurate in scope with the teachings of the instant specification, and thus anticipates the invention of the claims listed above.

Applicants argue that Alexeev discloses a chimeric oligonucleotide that contains both ribonucleotides and deoxyribonucleotides, but that the RNA components of this molecule, i.e., aauccaaacu and uuuccgcagu, are in the anti-sense orientation. As such, Applicants argue that Alexeev does not teach every limitation of claim 32. Although not explicitly stated, this argument depends upon the presumption that the term “mRNA” as defined in the specification requires the RNA to be in sense orientation. Applicants have pointed to page 3, lines 7-10 of the specification and to figure 7 in alleged support for a definition that the term “mRNA” refers to RNA only in the sense strand. At page 3, the relied upon citation is as follows:

“In one embodiment, the mRNA of the invention's hybrids is comprised of part or all of the unspliced mRNA transcript of the targeted gene. In another embodiment, the mRNA is comprised of part or all of the spliced mRNA transcript of the targeted gene. In yet another embodiment, the mRNA is comprised of a combination of part or all of the spliced and unspliced mRNA transcript of the targeted gene.”

This argument is not found persuasive. First, this definition is considered non-limiting, in that it does not *exclude* any embodiments, rather merely describing what is included. It does not prevent the term “mRNA” from being interpreted broadly as any RNA, which Alexeev clearly teaches. Second, this definition specifies that “part or all” mRNA is embraced within the term “mRNA”. Since “part” of the mRNA falls under the relied upon definition of mRNA, and since no lower length limit in relation to what “part” refers to, the term “mRNA” is considered to embrace any RNA fragment that is at least a dinucleotide in length that retains homology to some known mRNA. Thus, since every possible dinucleotide is represented in the total pool of mRNA's, any RNA sequence is broadly considered to include an “mRNA” sequence as broadly defined in the instant specification. The ribonucleotide sequence of the Alexeev molecule, therefore considered to meet the definition of mRNA as pointed to by applicants. Since the

Art Unit: 1635

remainder of applicant's arguments rely upon the presumption that Alexeev does not teach an mRNA in the sense orientation, and since this has not been adopted for reasons discussed above, both rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

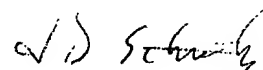
Art Unit: 1635

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JDS


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER